

Abstracts

379

whose core competencies involved the research and development (R&D) of pharmaceutical, medical, or biotechnological innovation. **METHODS:** Regression methods were utilized for a sample of 50 highly-innovative parent companies from 1985 to 1998. Dependent variables included stock market capitalization and returns. Independent variables included, but were not limited to, risk, patent activity, new molecular entity (NME) approvals, and R&D expenditures. **RESULTS:** Semi-elasticities of market capitalization with respect to firm-level determinants of innovative activity generally differed as a function of firm size. Measures of innovative output, including patents and NMEs, were significant only for the larger firm classifications, while R&D expenditures were significant for all group classifications. Smaller companies received higher relative valuations per million dollars spent on R&D than their larger rivals, and large firms received higher valuations based upon a one percent increase in R&D budgets. The analysis of stock market returns indicated that larger companies received returns, which were more consistently positive and less volatile, even though mean returns between groups were not statistically different. Accounting for the skewed nature of these data, the median returns differed substantially based upon firm size. The multivariate analysis of these returns did not reveal a trend that was consistent with either R&D inputs or outputs. **CONCLUSIONS:** Considerable differences in the valuation makeup of companies were observed between firm size. Diminishing semi-elasticities existed with respect to increasing firm size for many of the variables in the econometric analysis. Numerous phenomena appeared to impact stock market returns, indicating challenges in the appropriate valuation of companies concerning future R&D benefits, or that positive returns were not guaranteed even though overall R&D expenditures or innovative output increased.

PHP40

POST-LAUNCH STUDIES—WHAT IS DESIRABLE, WHAT IS FEASIBLE?

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OBJECTIVE: Given the increased interest in conducting pharmacoeconomics and outcomes studies post-launch, the objective of this study was to explore the desirability and feasibility of different types of studies. **METHODS:** The published literature on post-launch studies was reviewed and the recommendations for further research made by the National Institute for Clinical Excellence (NICE) in the UK were analysed. In addition, global heads of pharmacoeconomics and outcomes research (PE/OR) in major pharmaceutical companies were surveyed to ascertain their experience in conducting studies post-launch and the problems encountered. **RESULTS:** In the first 46 technology appraisal of drugs conducted by NICE, recommendations for further research included head-to-head studies of the new drug with relevant alternatives (39% of appraisals); better information on impacts on quality of life (43%); longer term evidence on compliance, adverse events or maintenance of clinical effect (41%); study of the drug in relevant patient sub-groups (33%); and understanding the most cost-effective use of the drug in routine practice (43%). The survey of heads of PE/OR departments revealed a wide variety of experience with conducting post-launch studies. The problems identified included the need for large sample sizes, difficulties in financing studies and the unfavourable risk-benefit of some studies from a commercial perspective. **CONCLUSIONS:** Whilst it is desirable to conduct pharmacoeconomics and outcomes research post-launch, those bodies recommending such studies should pay more attention to

the practical and methodological challenges raised by certain study designs.

PHP41

PARALLEL TRADE OF PHARMACEUTICALS AS A COST-CONTAINMENT MEASURE-ANALYSIS OF THE ISRAELI EXPERIENCE

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The Israeli Law enabling parallel import of pharmaceuticals was implemented in January 2001. Prior to its legislation there was only one exclusive importer for each pharmaceutical product, imported directly from the manufacturer. Parallel import enables the importation of a given pharmaceutical to Israel by a number of importers—not necessarily directly from the manufacturer, thus amplifying economic competition, which should result in lower acquisition price. **OBJECTIVES:** Our study examines the impact of the law three years after its implementation, regarding the national expenditure on pharmaceuticals. **METHODS:** Since financial data is not available to the public, the study was based on qualitative data. A survey of senior management of the Israeli health care system was conducted. A pool of 50 executives was constructed, representing all relevant stakeholders. Each participant was interviewed face-to-face, using a uniform questionnaire. **RESULTS:** The response rate was 68%, all sectors had at least one representative. The preliminary analysis of the answers shows that although during 3 years, only 22 drugs were parallel imported, most of the responders answered that both the national expenditure and prices of pharmaceuticals were reduced. No damage was done to the public's health, and there was no change in the number of newly approved pharmaceuticals. **CONCLUSIONS:** As a result of the Parallel Import legislation, combined with several other cost-containment reforms, a reduction in the prices of pharmaceuticals is noticed. The fact that only 22 pharmaceuticals, and none during 2003, were actually imported by parallel trade shows that the main reduction is attributed to lower prices established by the manufacturers themselves, trying to avoid competition from parallel imports. Thus, the importance of the law lies not necessarily by carrying it out, but simply by the fact that it allows the major buyers to use it as a tool in the negotiation with manufacturers.

PHP42

METHODS FOR “GO/NO-GO” MODELING OF COMPOUNDS IN THE DEVELOPMENT PIPELINE

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OBJECTIVE: Although drug manufacturers have gained competence in pharmacoeconomic analysis, they have been slow to bring these tools and techniques to bear on important “go/no-go” decisions for compounds in development. This may be due to difficulties in modeling the cost-effectiveness of products that have yet to undergo clinical trials, wherein critical data on important model parameters would be collected. Yet, in the current cost-conscious environment, it is risky to invest in the development of a product without first exploring its potential pharmacoeconomic profile. **METHOD:** We developed an analytic apparatus for use in conjunction with traditional cost-effectiveness models to illustrate how good a developmental compound would need to be in terms of key clinical parameters (e.g., adverse event rate, failure rate) for it to be cost-effective versus competing products. Borrowing constructs from micro-economic theory, we demonstrate how two-way threshold analy-